

With that said, reconsideration and withdrawal of the Examiner's requirement for restriction is respectfully requested in light of the following remarks.

REMARKS

Restriction may be required if two or more "independent and distinct" inventions are claimed in one application. 35 U.S.C. § 121; 37 C.F.R. § 1.141. However, Applicants submit that the main purpose of Rule 141 is to facilitate the search in considering the patentability of the claimed subject matter and to avoid a situation that requires separate and diverse searches to be conducted on claims directed to independent (unrelated) subject matter. Inventions are deemed "independent" if there is no disclosed relationship and/or if the inventions are unconnected in design, operation or effect. See M.P.E.P. § 802.01.

The Patent Office practice as set forth in the MPEP requires that search and examination of the entire application must impose a serious burden on the Examiner before a proper requirement for restriction may be made. MPEP 803, page 800-4, col. 1 (third paragraph in MPEP 803). Thus, the Patent Office encourages the assertion that examination of the entire application may take place where such search and examination can be made without serious burden, even though separate, non-overlapping searches may be required.

The Examiner asserts that the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to the Examiner, "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Citing Mears (1985, U.S. Patent 4,553,272), which allegedly teaches a surgical implant comprising a porous surgical steel implant in which are seeded cartilage and bone cells for the purpose of bone and joint reconstruction surgery, the Examiner concluded that the inventions of Group I – III are not related to a single general inventive concept. Applicants respectfully contend that the asserted reason is in error and that the Examiner has not met the conditions for a proper restriction requirement.

Unlike the alleged teaching of Mears (U.S. 4,553,272), the alleged “independent and distinct” inventions of Groups I – III relate to a joint construct having two layers on the carrier material, namely a cartilaginous tissue layer on top of an osseous tissue layer which anchors the cartilaginous tissue layer to the bone shaft. Mears did not teach nor suggest this bilayer model. Moreover, the carrier material of the implant described by Mears is selected from materials consisting essentially of metal alloys or graphite composites (see column 3, lines 48-54), whereas the carrier materials of the present invention are biocompatibles having no cytotoxic effects and allow proliferation and differentiation of cells to produce tissue synthesizing cells. (See specification page 3, lines 1-15.) For at least this bilayer model on a biocompatible carrier, Applicants assert that the general inventive concept of the instant application has special technical feature(s) not known in the art, and to which all the claims of the instant invention relate.

Thus, the restriction requirement is deficient in that the Examiner has not shown that the involved claims are directed to independent inventions. Moreover, that search and examination of the entire application must impose a serious burden on the Examiner before a proper requirement for restriction may be made. Applicants do not believe that a serious burden on search and examination exists in this case because the inventions relate to a general inventive concept.

For instance, Group II claims as asserted by the Examiner, are drawn to a joint replacement comprising two or more joint constructs of Group I. If Group II claims are thereby distinct from Group I, as the Examiner concluded, Applicants respectfully assert that the rule requires them to be not only distinct, but independent as well, in order to meet the proper requirements for restriction. If the alleged restrictable inventions are not independent and distinct, the Examiner has not made a prima facie showing of serious burden on search and examination. Applicants believe that a reasonable search for joint constructs of Group I would necessarily lead to disclosures, to the extent any exist, of the compounded joint constructs of Group II.

Regarding Group III drawn to processes for producing biological joint constructs of the present invention, the Examiner asserts that Groups I and III are unified only by the biological joint constructs of Group I, which allegedly is well known in the art, and thus do not relate to a single general inventive concept. Applicants respectfully disagree.

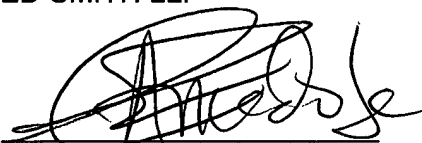
For at least the foregoing, the biological joint constructs of the present invention are not well known. Moreover, a process claim, without more, does not impose a serious burden on search and examination when joined with the underlying product claim. That is why M.P.E.P. § 821.04 permits a rejoinder of process claims that depend from or otherwise include all the limitations of allowable product claims. In view of that, the restrictability of Group III and Group I claims is improper and the Examiner is requested to withdraw this requirement.

Further regarding Group III in relation to Group II, allegedly unified only by the composition of allegedly well known Group I, Applicants again respectfully disagree that the Examiner's assertion has cured the deficiency in this requirement for restriction. Not only is Group I not well known in the art, the general inventive concept of a bilayer model anchored on a biocompatible carrier sufficiently unifies all the claims of the present invention, and particularly Group II and III claims, as to render the basis for this restriction requirement patently in error.

Applicants further submit that since the examiner has not shown the existence of separate classification, or separate status in the art, or a different field of search under M.P.E.P. 808.02, the Examiner has not made a prima-facie showing of a serious burden and it is, therefore, incumbent upon the Examiner to conduct such a search. Accordingly, Applicants request that the Examiner reconsider and withdraw this restriction requirement.

Respectfully submitted,

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